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8 UNITED STATES DISTRICT COURT  
9 NORTHERN DISTRICT OF CALIFORNIA  
10 SAN FRANCISCO DIVISION

12 UNITED STATES OF AMERICA,

13 Plaintiff,

14 v.

16 INTERMUNE, INC.,

17 Defendant.

No. CR 06-0707 JSW

VIOLATION: 21 U.S.C. §§ 331(k),  
333(a)(2) - Misbranding

SAN FRANCISCO VENUE

**[PROPOSED] DEFERRED  
PROSECUTION AGREEMENT**

21 **DEFERRED PROSECUTION AGREEMENT**

22 InterMune, Inc. ("InterMune"), by its undersigned officer, and the Department of Justice,  
23 by the United States Attorney's Office for the Northern District of California (the "Department"),  
24 enter into this Agreement in resolution of the Department's ongoing criminal investigation into  
25 matters relating to the promotion of the pharmaceutical product Actimmune® (interferon  
26 gamma-1b) by InterMune from a time period spanning 2000 to 2003.

27 For purposes of this Agreement, the relevant time period is from August 2002 through  
28

ORIGINAL  
FILED  
OCT 25 2006  
RICHARD W. WYKING  
CLERK, U.S. DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

1 January 2003 (the "Investigative Period"). The effective date of this Agreement will be the date  
2 that it is accepted by the Court for the Northern District of California.

3 This Agreement is binding upon InterMune, Inc. and the Attorney General for the United  
4 States, the United States Department of Justice, and all United States Attorneys. This Agreement  
5 does not bind the Tax Division of the U.S. Department of Justice or the Internal Revenue Service  
6 of the U.S. Department of the Treasury. InterMune, Inc. understands that this Agreement does  
7 not bind any state or local prosecutive authorities.

### 8 9 INFORMATION

10 1. The United States will file an Information in the United States District Court for  
11 the Northern District of California charging InterMune with One Count of doing an act, with  
12 intent to defraud or mislead, with respect to a drug while the drug was held for sale after  
13 shipment in interstate commerce that resulted in the drug being misbranded, in violation of Title  
14 21, United States Code, Sections 331(k) and 333(a)(2) (the "Information").

### 15 16 THE DEPARTMENT'S INVESTIGATION

17 2. During the course of the investigation, the Department notified InterMune that  
18 certain former InterMune personnel violated federal criminal law, specifically that certain former  
19 InterMune employees promoted Actimmune® for unapproved indications and made misleading  
20 statements regarding Actimmune in violation of: (a) the Federal Food, Drug and Cosmetic Act,  
21 21 U.S.C. § 331; and (b) Health Care Fraud, 18 U.S.C. § 1347. As described more fully below,  
22 InterMune has provided extensive cooperation to the Department in this investigation.

23 3. InterMune does not contest that the Department has developed evidence during its  
24 investigation that one or more former InterMune employees violated federal criminal law during  
25 the Investigative Period. One or more former InterMune employees instructed certain members  
26 of the Actimmune sales force and a specialty pharmacy to promote Actimmune for idiopathic  
27 pulmonary fibrosis, an indication other than those for which the drug had received FDA  
28 approval. InterMune acknowledges that part of the Department's investigation is set forth in

1 Attachment A and does not contest the facts set forth in Attachment A. InterMune accepts  
2 responsibility for the conduct of its former employees and conduct its former employees directed.  
3 InterMune does not endorse, ratify or condone criminal conduct, and, as set forth below, has  
4 taken steps to prevent such conduct from occurring in the future.  
5

6 COOPERATION AND REMEDIAL MEASURES

7 4. InterMune provided substantial cooperation and assistance to the Department's  
8 investigation.

9 A. First, InterMune disclosed the results of internal investigations that had occurred  
10 prior to the Department's investigation and related to the conduct set forth in  
11 Attachment A.

12 B. Second, InterMune fully complied with the subpoena served by the Department  
13 and provided significant information regarding the conduct of certain former  
14 employees and officers.

15 C. Third, InterMune made numerous presentations that were helpful to the  
16 Department's investigation.

17 D. Fourth, InterMune made certain current employees and officers who were  
18 employed by the Company during the period of investigation available to the  
19 Department in connection with its investigation.

20 InterMune has agreed to, and will, continue to fully cooperate with the Department as may be  
21 reasonably required during the term of this agreement, which is two (2) years from the effective  
22 date of this Agreement.

23 5. InterMune's management team -- the great majority of whom were hired after the  
24 Investigative Period -- also instituted numerous and comprehensive compliance changes,  
25 including new compliance policies, audits and internal reviews, and revised sales representative  
26 compensation programs. These compliance changes were instituted by the Company prior to the  
27 commencement of the Department's investigation.

AGREEMENT

6. Based upon InterMune's significant cooperation and the corrective measures it has implemented, and InterMune's commitment to implement and audit such measures and its willingness to continue to cooperate with the Department in its investigation of these matters, the Department, on the understandings specified below, agrees that the Department shall recommend to the Court that prosecution of InterMune on the Information be deferred for a period of two (2) years from the effective date of this Agreement (the "Effective Period"). InterMune shall expressly waive all rights to a speedy trial pursuant to the Sixth Amendment of the United States Constitution, Title 18, United States Code, Section 3161, Federal Rule of Criminal Procedure 48(b), and any applicable Local Rules of the United States District Court for the Northern District of California for the period during which this Agreement is in effect.

7. The Department agrees that if InterMune is in compliance with all of its obligations under this Agreement, the Department will, within 30 days of the expiration of two (2) years from the effective date of this Agreement, seek dismissal with prejudice of the Information filed against InterMune pursuant to paragraph 1 of this Agreement, and this Agreement shall expire. Except in the event of a breach of this Agreement, the Department will bring no additional criminal charges against InterMune relating to or arising out of matters set forth in the Information or in Attachment A or the promotion of Actimmune during the period 2000 through 2003; the Department acknowledges that this Agreement protects InterMune from indictment and/or trial as to such matters. InterMune and the Department understand that the Agreement to defer prosecution of InterMune must be approved by the Court, in accordance with 18 U.S.C. § 3161(h)(2). Should the Court decline to approve the Agreement to defer prosecution for any reason, both the Department and InterMune are released from any obligation imposed upon them by this Agreement, and this Agreement shall be null and void.

8. This Agreement does not provide any protection to any former employee of InterMune or any other entity, except successor entities as described in Paragraph 19, below. InterMune understands and agrees that if it violates this Agreement, the Department can prosecute

1 InterMune for any crimes committed by its employees, officers or directors relating to the  
2 promotion of Actimmune®.

3 The understandings on which this Agreement are premised are:

4 9. For the Effective Period, InterMune shall continue to fully cooperate with the Department  
5 regarding any matter relating to the Department's investigation of the promotion of Actimmune  
6 about which InterMune has information or knowledge, including, but not limited to, the  
7 following: (a) InterMune shall truthfully disclose all information of which it may be aware with  
8 respect to the activities of InterMune, its directors, officers and employees, about which the  
9 Department shall inquire; (b) InterMune shall provide to the Department, on written request, any  
10 document, record or other tangible evidence, including but not limited to information and  
11 documents concerning presentations, publications, and patient registries, about which the  
12 Department shall inquire; (c) InterMune shall provide to the Department reasonable access to  
13 InterMune's facilities, documents and employees. In addition,

14 A. InterMune will use its best efforts to continue to make records and witnesses  
15 available during the Effective Period regarding activities of the Company during  
16 the Investigative Period, provided, however, this agreement to cooperate does not  
17 apply to any information provided by InterMune to legal counsel after May 1,  
18 2004 in connection with the provision of legal advice and the legal advice itself,  
19 and nothing in this Agreement shall be construed to require InterMune to provide  
20 any such information or advice to the Department.

21 B. This agreement by InterMune to cooperate shall not be construed as a waiver with  
22 respect to third parties of the attorney-client privilege, work-product protection, or  
23 any other privilege applicable to information or documents provided to the  
24 Department pursuant to this Agreement; InterMune neither expressly nor  
25 implicitly waives its right to assert any privilege that may be available against  
26 entities other than the Department of Justice.

1 C. This agreement to cooperate shall not apply in the event that the Department  
2 pursues a criminal prosecution against InterMune.

3 10. Upon request of the Department, with respect to any issue relevant to its investigation of  
4 the promotion of Actimmune at any time (not limited to the Investigative Period), InterMune  
5 shall designate knowledgeable employees, agents or attorneys to provide non-privileged  
6 information and/or materials on InterMune's behalf to the Department. It is further understood  
7 that InterMune must at all times give complete, truthful and accurate information to the  
8 Department.

9 11. With respect to any information, testimony, document, record or other tangible evidence  
10 relating to the promotion of Actimmune provided by InterMune to the Department or a grand  
11 jury, InterMune consents to any and all disclosures to governmental law enforcement entities of  
12 such materials as the Department, in its reasonable discretion and in good faith, deems  
13 appropriate. With respect to any such materials that constitute "matters occurring before the  
14 grand jury" within the meaning of Rule 6(e) of the Federal Rules of Criminal Procedure,  
15 InterMune further consents to a) any order sought by the Department permitting such disclosure  
16 and b) the Department's ex parte or in camera application for such orders. The Department  
17 agrees that any material which comprises trade secrets or other proprietary information shall,  
18 prior to disclosure to any governmental entity, be redacted of such information, or be  
19 accompanied by a prominent warning notifying the agency of the protected status of the material.  
20 Nothing in this paragraph shall be construed as a waiver of InterMune's rights in the materials it  
21 provides to the Department, and such materials shall not be provided to non-governmental  
22 entities without InterMune's prior written consent.

23 12. InterMune agrees that it will use its best efforts to not make any public statements, in  
24 litigation or otherwise, materially contradicting the facts set forth in Attachment A, or its  
25 representations in this Agreement. Any such statements shall constitute a breach of this  
26 Agreement, and InterMune thereafter would be subject to prosecution unless it cures its breach as  
27 set forth below. Upon the Department's providing written notice to InterMune of such a

28 Deferred Prosecution Agreement

1 contradictory statement, InterMune may avoid a breach of this Agreement by publicly  
2 repudiating such statement within 72 hours after receipt of written notification by the  
3 Department.

4 13. InterMune is simultaneously entering into an agreement with the Department's Civil  
5 Division (the "Civil Settlement Agreement") regarding the payment of money to settle certain  
6 civil claims. InterMune is also simultaneously entering into a Corporate Integrity Agreement  
7 ("CIA") with the Office of Inspector General of the Department of Health and Human Services  
8 ("OIG-HHS") to implement certain specified compliance measures. Failure by InterMune to  
9 comply fully with those material terms of the Civil Settlement Agreement called to occur during  
10 the Effective Period of this Agreement may constitute a breach of this Agreement, provided,  
11 however, that a breach of the CIA referenced in the Civil Settlement Agreement does not  
12 constitute a breach of this Agreement. Any disputes arising under the CIA shall be resolved  
13 exclusively through the dispute resolution provisions of the CIA. The parties understand that  
14 nothing in this paragraph shall be construed to enlarge the Effective Period of this Agreement, or  
15 to delay the dismissal of the Information as described in paragraph 7 if at the time specified  
16 therein, InterMune is in full compliance with its obligations under the Civil Settlement  
17 Agreement. The parties further understand and agree that this paragraph does not deprive  
18 InterMune of its rights under the Civil Settlement Agreement or the common law to contest the  
19 existence of a breach of the Civil Settlement Agreement in the Northern District of California.  
20 The Department further agrees that nothing in this paragraph shall be construed by the United  
21 States as affecting the underlying nature of InterMune's obligations under the Civil Settlement  
22 Agreement.

23 14. It is further understood that should it be determined that InterMune has deliberately given  
24 materially false, incomplete, or misleading information under this Agreement, or has committed  
25 any criminal health care fraud offense during the Effective Period, or that InterMune has  
26 otherwise knowingly, intentionally and materially violated any provision of this Agreement,  
27 InterMune shall, in the Department's reasonable discretion and in good faith, thereafter be

28 Deferred Prosecution Agreement

1 subject to prosecution for any federal criminal violation of which the Department has knowledge.  
2 Any such prosecutions may be premised on information provided by InterMune to the  
3 Department. Moreover, InterMune agrees that any criminal prosecutions relating to the unlawful  
4 promotion of Actimmune from 2000 through 2003 that are not time-barred by the applicable  
5 statute of limitations on the effective date of this Agreement may be commenced against  
6 InterMune in accordance with this Agreement, notwithstanding the expiration of the statute of  
7 limitations between the effective date of this Agreement and its expiration date two years after  
8 the date this Agreement is accepted by the Court. By this Agreement, InterMune expressly  
9 intends to and does waive any rights with respect to the statute of limitations as described in the  
10 preceding sentence.

11 15. It is further agreed that should it be determined that InterMune has knowingly,  
12 intentionally and materially violated any provision of this Agreement:

- 13 A. all statements made by InterMune to the Department, FDA, HHS-OIG, the FBI or  
14 any other federal agency, or any testimony given by InterMune before a grand  
15 jury, the United States Congress, the SEC, or elsewhere, whether prior or  
16 subsequent to this Agreement, including this Agreement and the statement of facts  
17 in Attachment A, shall be admissible in evidence in any and all criminal  
18 proceedings brought by the Department against InterMune;
- 19 B. nothing in this agreement shall prohibit the admission in such proceedings of any  
20 evidence derived from such statements or testimony; and
- 21 C. InterMune shall not assert any claim under the United States Constitution, Rule  
22 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules  
23 of Evidence, or any other federal rule, that statements made by InterMune prior to  
24 or subsequent to this Agreement, or any leads therefrom, should be suppressed.

25 16. In the event the Department asserts that InterMune has breached any provision of this  
26 Agreement, the Department shall provide written notice to InterMune and will provide  
27 InterMune with a two-week period from receipt of such notice, except as otherwise specified



1 herein, in which to make a presentation to the Department, or its designee, to demonstrate that no  
2 breach has occurred, or, to the extent applicable, that the breach was not knowing, intentional or  
3 material, or has been cured. The Department shall have four weeks from providing written  
4 notice to InterMune asserting a breach to file a motion with the Court asserting the breach and  
5 seeking a finding of a breach; however, this motion shall not be filed less than 15 days from the  
6 day the Department provides InterMune written notice asserting the breach. In the event a  
7 motion is filed by the Department, the Court shall determine whether a breach occurred by a  
8 preponderance of the evidence.

9 17. InterMune agrees to not enter into any joint defense agreements relating to the  
10 Department's investigation during the Effective Period of this Agreement without Department  
11 approval, and InterMune further agrees to withdraw from current joint defense agreements, if any  
12 exist, for which the Department does not approve of InterMune's continuing participation. The  
13 Department agrees that its approval pursuant to this paragraph will not be unreasonably withheld.

14 18. The Company agrees that if it sells or merges all or substantially all of its business  
15 operations as they exist as of the date of this Agreement to or into a single purchaser or group of  
16 affiliated purchasers during the term of this Agreement, it shall provide the Government with  
17 reasonable prior notice and it shall include in any contract for sale or merger a provision binding  
18 the purchaser-successor to the obligations described in this Agreement.

19 19. With respect to the matters described in this Agreement, and with the exception of the  
20 agreements described in paragraph 13, and the letter from Ethan M. Posner to the Department  
21 dated October 9<sup>th</sup>, 2006, this Agreement supersedes all prior, if any, understandings, promises,  
22 and/or conditions between the Department and InterMune. This Agreement may not be modified  
23 except in writing signed by all the parties.

24 20. InterMune hereby warrants and represents that the Board of Directors of InterMune has  
25 duly authorized, in a specific resolution, the execution and delivery of this Agreement by  
26 InterMune, and that the person signing the Agreement has authority to bind InterMune.

27 InterMune agrees that either a duly authorized corporate officer or a duly authorized attorney for

1 InterMune, at the discretion of the Court, shall appear on behalf of InterMune to enter into this  
2 Agreement.  
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DATE \_\_\_\_\_

Ioana Petrou  
Assistant United States Attorney

DATE \_\_\_\_\_

Robin Steele  
Senior Vice President and General Counsel  
InterMune, Inc.  
3280 Bayshore Boulevard  
Brisbane, CA 94005

DATE \_\_\_\_\_

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1 On Behalf of the United States Department of Justice:  
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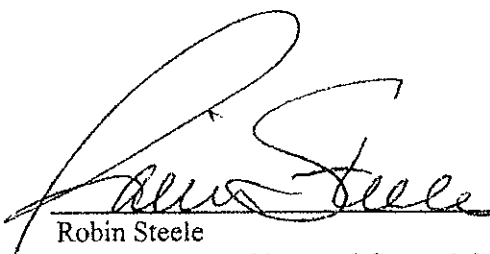
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Kevin V. Ryan  
United States Attorney  
Northern District of California

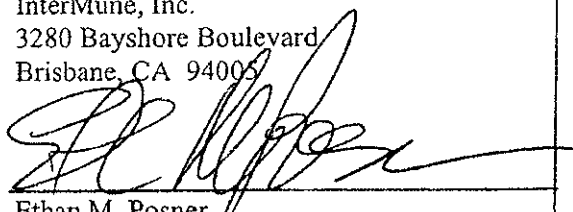
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Assistant United States Attorney  
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12 On Behalf Of InterMune, Inc.  
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15 October 24, 2006  
16 DATE

  
Robin Steele  
Senior Vice President and General Counsel  
InterMune, Inc.  
3280 Bayshore Boulevard  
Brisbane, CA 94005

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19 10-24-06  
20 DATE

  
Ethan M. Posner  
Covington & Burling  
Counsel to InterMune, Inc.  
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# Attachment A

1  
2 **Attachment A**

3 **Introduction**

4 InterMune, Inc., first incorporated in 1998, is a biopharmaceutical company focused on  
5 developing and commercializing innovative therapies in pulmonology and hepatology.

6 During the Investigative Period (August 2002 through January 2003), InterMune derived  
7 the majority of its revenue from Actimmune® (interferon gamma-1b). Actimmune was  
8 approved by the United States Food and Drug Administration ("FDA") for the treatment of  
9 chronic granulomatous disease and severe, malignant osteopetrosis. These diseases affect very  
10 small patient populations. The vast majority of Actimmune sales during the Investigative Period  
11 were attributable to prescriptions for the treatment of idiopathic pulmonary fibrosis ("IPF"), a  
12 debilitating, fatal lung disease for which there is no FDA-approved treatment and which afflicts  
13 approximately 83,000 Americans.

14 **Dissemination of Misleading Information Regarding Phase III Trial of Actimmune**

15 1. Commencing in October 2000 and through 2002 InterMune conducted a global  
16 Phase III clinical trial of Actimmune for the treatment of IPF that was designed to study whether  
17 Actimmune extended the time to disease progression or death. The primary endpoint was  
18 progression-free survival, measured from randomization of the test subjects either to disease  
19 progression or death, and, in addition, there were a number of secondary endpoints, including  
20 overall patient survival. In this clinical study, 330 IPF patients were studied in a double-blind,  
21 placebo-controlled trial conducted at 58 centers in the United States and Europe. Study  
22 participants received either a placebo or 200 micrograms of Actimmune injected subcutaneously  
23 three times per week. All patients were to remain in the trial until the last patient received 48  
24 weeks of therapy. Median treatment duration was 60 weeks.

25 2. On August 16, 2002, a select number of InterMune personnel received data from  
26 the clinical trial. On August 19, 2002, the data was also provided to the Data Monitoring  
27 Committee ("DMC"), which had been established in accordance with the protocol of the trial as  
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1 an independent committee that monitored safety and efficacy data throughout the trial in order to  
2 determine if it was scientifically and ethically appropriate to continue the trial, and to review data  
3 from the completed trial. The data showed that the trial failed to achieve statistical significance  
4 on the primary endpoint agreed between InterMune and the FDA, or any agreed upon secondary  
5 endpoint, including overall survival. After receiving the data, InterMune conducted some  
6 additional analysis of the mortality data that involved breaking the patient population into  
7 subgroups.

8 3. Certain senior InterMune personnel discussed these preliminary trial results,  
9 including the exploratory subgroup analysis, with representatives of the FDA in an informal  
10 telephone conference on August 27, 2002. The purpose of the call was to provide InterMune  
11 with the FDA reviewers' preliminary impressions of the data. The FDA representatives told  
12 InterMune that any substantive comments represented their own opinions and did not reflect the  
13 official opinion of the FDA. During the telephone conference, one FDA representative noted that  
14 the study failed to demonstrate efficacy on its primary endpoint. The FDA representative  
15 suggested that while the data appeared to show an optimistic trend on overall survival, because  
16 the data had failed to achieve statistical significance in the primary endpoint previously agreed  
17 with the FDA at the outset of the trial, it was the representative's opinion that the FDA was  
18 unlikely to approve the use of Actimmune for the treatment of IPF without further rigorous  
19 clinical testing.

20 4. On August 28, 2002, InterMune publicly announced the results of the Phase III  
21 clinical trial of Actimmune for the treatment of IPF in the form of a press release. Former  
22 employees of InterMune approved the press release, which was headlined "InterMune Announces  
23 Phase III Data Demonstrating Survival Benefit of Actimmune in IPF, with the subheading  
24 "Reduces Mortality by 70% in Patients With Mild to Moderate Disease." In the release,  
25 InterMune's then-President and CEO characterized the clinical trial results as indicating that  
26 "Actimmune may extend the lives of patients suffering from this debilitating disease" and further  
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1 stated that "Actimmune is the only available treatment demonstrated to have clinical benefit in  
2 IPF, with improved survival data in two controlled clinical trials."

3 5. By letter dated September 5, 2002 to InterMune, the Chair of the DMC expressed  
4 his "serious concerns" with the August 28, 2002 press release. The letter reminded InterMune of,  
5 "the DMC's assessment that the trial had failed to establish benefit on the primary endpoint" and  
6 that there was no statistically significant evidence of benefit for any of the secondary endpoints.  
7 The letter also stated that the press release provided a "serious misrepresentation of results  
8 obtained from exploratory data subgroup analyses," referring specifically to the subheading and  
9 other statements concerning a survival benefit in the mild to moderate subgroup.

10 6. In approximately mid-October 2002, a specialty pharmacy that distributed  
11 Actimmune disseminated a fax concerning Actimmune for IPF to more than 2,000  
12 pulmonologists. Distribution of the fax had been approved by a former InterMune employee.  
13 The fax, like the August 28, 2002 press release, began with the headline, "InterMune Announces  
14 Phase III Data Demonstrating Survival Benefit of Actimmune in IPF," and continued with the  
15 subheading, "Reduces Mortality by 70% in Patients with Mild to Moderate Disease." The fax  
16 also included a copy of the InterMune press release.

17 7. During approximately September to October 2002, the same specialty pharmacy,  
18 again with the approval of a former InterMune employee, distributed a patient letter by mail to  
19 Actimmune patients, which was sent along with their Actimmune prescriptions. The patient  
20 letter was prepared by the specialty pharmacy's clinical staff from information, including the  
21 press release, provided by former InterMune personnel and provided the same misleading  
22 information about the results of the Phase III Actimmune trial results. The letter stated that "On  
23 August 28, 2002, InterMune, Inc. announced that preliminary data from its Phase III clinical trial  
24 of Actimmune (Interferon gamma-1b) injection for the treatment of [IPF] showed a statistically  
25 significant reduction in mortality by 70% in patients with mild to moderate IPF. Interferon  
26 gamma-1b is the first treatment ever to show any meaningful impact in this disease in clinical  
27 trials. These results indicate that Actimmune should be used early in the course of treatment of  
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1 this disease in order to realize the most favorable long-term survival benefit.” A former  
2 InterMune employee approved the final version of the patient letter.

3           8. Notwithstanding the fact that the Phase III trial failed to establish statistically  
4 significant benefits on its primary endpoint or any of its secondary endpoints, including overall  
5 survival, and notwithstanding the evaluation of the results by the FDA and DMC, certain former  
6 InterMune employees encouraged InterMune sales force personnel to inform physicians that  
7 Actimmune demonstrated a survival benefit in mild to moderate IPF patient populations, and  
8 certain former sales force personnel did so. Certain former sales personnel also distributed or  
9 showed the specialty pharmacy documents to physicians during sales visits.

10 ASAP Registry

11           9. In 2001, InterMune established the “Actimmune Safe and Appropriate Use  
12 Program” (the “ASAP Registry” or the “Registry”), a registry that collected information about  
13 IPF patients taking Actimmune. As described in the Registry Services Agreement between  
14 InterMune and the third-party administrator of the Registry, the ASAP Registry was an  
15 observational database designed to obtain data on “variation in current diagnostic and therapeutic  
16 management of patients receiving Actimmune.” Information from the Registry was to be  
17 available “to InterMune and to participating physicians for research and analysis” and “as a basis  
18 for scientific presentations and publications.”

19           10. During the Investigative Period, the ASAP Registry was operated substantially by  
20 InterMune sales and marketing personnel. During the Investigative Period, InterMune sales  
21 representatives were the principal source of Registry enrollment, and were also the principal  
22 points of contact for physicians and their offices with respect to the Registry. Sales  
23 representatives received incentive payments for patients they enrolled.

24           11. Although one purpose the ASAP Registry was to gather data on Actimmune  
25 patients and make that data available to physicians who had patients enrolled in the Registry,  
26 InterMune did not share the data directly with physicians. InterMune provided a brief summary  
27 presentation at a scientific meeting in late 2002 in San Diego.

1           12. During the Investigative Period, there were a number of regulatory and operational  
2 issues raised by the third-party administrator concerning the ASAP Registry, including various  
3 issues relating to good clinical practices and the extent of InterMune sales representatives'  
4 participation in the operation of the Registry.

5           13. In the spring of 2002, an outside consultant was retained by InterMune to assess  
6 the ASAP Registry. In June 2002, the consultant issued a final audit report, which identified a  
7 number of problems with the Registry and concluded that absent significant changes, data from  
8 the Registry would most likely not be accepted by the regulatory authorities.

9           Sales Force

10           14. InterMune employed approximately sixty sales representatives focusing on  
11 pulmonology and, in particular, Actimmune, during the Investigative Period. The FDA had not  
12 approved Actimmune for the treatment of pulmonary disorders at that time.

13           15. In January 2001, InterMune acquired rights to Amphotec®, an anti-fungal drug  
14 approved by the FDA for the treatment of aspergillosis, including pulmonary aspergillosis.  
15 Amphotec was primarily administered in a hospital setting. Prior to the fall of 2002, InterMune's  
16 sales representatives had not marketed Amphotec for pulmonary aspergillosis outside the hospital  
17 setting. However, in the fall of 2002, sales force personnel relied on Amphotec for access to  
18 pulmonologists' offices, where the primary purpose for access to the offices was to discuss  
19 Actimmune for IPF.

20           16. InterMune's Sales Incentive Compensation Plan for 2002 provided that sales  
21 representatives would receive a quarterly bonus based on 7% of incremental Actimmune sales  
22 and 3.5% of incremental Amphotec sales. The Plan also provided that the bonuses paid to  
23 Regional Sales Directors were derived in part from the total earnings of the sales representatives  
24 in their regions.

25           17. During the Investigative Period several sales force personnel sometimes created  
26 and used their own marketing aids in discussions with physicians concerning Actimmune for IPF.  
27 For example, one former sales representative wrote and distributed an invitation letter to an  
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1 educational program, which one physician recipient characterized as “against the spirit of FDA  
2 regulations.”  
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# Attachment B

**Attachment B - CIVIL SETTLEMENT AGREEMENT**

**REDACTED**

## CIVIL SETTLEMENT AGREEMENT

### I. PARTIES

This Settlement Agreement ("Agreement") is entered into by and between the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the Northern District of California, on behalf of the Office of Inspector General ("OIG-HHS") of the United States Department of Health and Human Services ("HHS"); the United States Office of Personnel Management ("OPM"); the United States Department of Defense TRICARE Management Activity ("TMA"); the United States Department of Defense, Defense Logistics Agency ("DLA"), on behalf of the Defense Supply Center- Philadelphia ("DSCP") (collectively "the United States"); InterMune, Inc. ("InterMune"), a Delaware corporation with its principal place of business in Brisbane, California; and [REDACTED] (hereafter referred to as "the Parties"), through their authorized representatives.

### II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. WHEREAS, at all relevant times, InterMune distributed, marketed and sold pharmaceutical products in the United States, including a drug it sold under the trade name Actimmune®;

B. WHEREAS, on or about July 9, 2004, [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]

C. WHEREAS InterMune has agreed to enter into a Deferred Prosecution Agreement ("DPA") with the United States Attorney for the Northern District of California. The United States has filed an Information in the United States District Court for the Northern District of California (the "Court") charging InterMune with One Count of doing an act, with intent to defraud or mislead, with respect to a drug while the drug was held for sale after shipment in interstate commerce that results in the drug being misbranded, in violation of Title 21, United States Code, Section 331(k) (the "Information");

D. WHEREAS, the United States and InterMune will file with the Court the DPA, which states that the Department of Justice will recommend to the Court that prosecution of InterMune for the conduct charged in the Information be deferred for a period of 2 years from the date the Court approves the DPA and that the Department of Justice will seek dismissal with release of the Information thereafter if InterMune is in compliance with all of its obligations under the DPA;

E. WHEREAS, InterMune has entered into or will be entering into separate settlement agreements ("Medicaid State Settlement Agreements") with the states which will be receiving settlement funds from InterMune pursuant to Paragraph 1(c) below for the Covered Conduct described in Paragraph G below (hereinafter referred to as the "Medicaid Participating States");

F. WHEREAS, the United States and the Medicaid Participating States allege that InterMune caused to be submitted claims for payment for Actimmune to Medicaid Programs,

established pursuant to or in connection with Title XIX of the Social Security Act ("Act"), 42 U.S.C. §§ 1396-1396y (the "Medicaid Program"); and the United States further alleges that InterMune caused to be submitted claims for payment of Actimmune to the Medicare Program, 42 U.S.C. §§ 1395-1395hhh, TRICARE Program (formerly known as the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS")), 10 U.S.C. §§ 1071-1110, which is administered by the Department of Defense through TMA, and to the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C. §§ 8901-8914, and that InterMune caused purchases of Actimmune by the Department of Veterans Affairs ("DVA") and DSCP;

G. WHEREAS, the United States contends that it has claims under the False Claims Act, 31 U.S.C. §§ 3729-3733, and that it and the Medicaid Participating States (hereinafter collectively referred to as the "Government") have certain other civil claims against InterMune for allegedly engaging in the following conduct with respect to the marketing, promotion and sale of Actimmune:

(i) The Government contends that between January 1, 2001 and June 30, 2003, InterMune knowingly and willfully promoted the sale and use of Actimmune for the treatment of idiopathic pulmonary fibrosis ("IPF"), a use for which Actimmune had not been approved by the United States Food and Drug Administration ("FDA"), and knowingly caused the submission of claims to the Government as described in subparagraph (v) below.

Actimmune has only been approved by the FDA to treat two rare diseases, chronic granulomatous disease and severe, malignant osteopetrosis;

(ii) The Government contends that notwithstanding the fact that InterMune's



Phase III clinical trial of Actimmune for the treatment of IPF failed to establish statistically significant benefits on its primary endpoint or any of its secondary endpoints, including overall survival, certain former InterMune employees encouraged InterMune sales force personnel to inform physicians that Actimmune demonstrated a survival benefit in mild to moderate IPF patient populations, and certain former sales force personnel did so;

(iii) The Government contends that InterMune's promotion of Actimmune for IPF violated the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(a) & (d);

(iv) The Government contends that the use of Actimmune for IPF was not a "medically accepted indication" pursuant to 42 U.S.C. § 1396r-8(k)(6);

(v) The Government further contends that the conduct described in the foregoing subparagraphs (i) through (iv) resulted in claims for Actimmune being submitted to the Medicaid, Medicare, FEHBP and TRICARE Programs, and in DVA and DSCP purchasing Actimmune for dispensing to patients for an unapproved indication, between January 1, 2001 and June 30, 2005, in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733.

InterMune's conduct as described in the Civil Action, the DPA and in Preamble Paragraph G of this Agreement is hereafter referred to as the "Covered Conduct."

H. WHEREAS, the United States also contends that it has certain administrative claims against InterMune for engaging in the Covered Conduct, as specified in Paragraphs 5-8 below;

I. 

[REDACTED]

J. [REDACTED]

[REDACTED]

K. WHEREAS, this Agreement is neither an admission of facts or liability by InterMune (with the exception of such admissions as InterMune makes in connection with the DPA referenced in Paragraph C above and accepted by the Court) nor a concession by the Government that its claims are not well founded; and

L. WHEREAS, to avoid the delay, expense, inconvenience and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth in this Agreement.

### III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. InterMune shall pay to the United States and the Medicaid Participating States, collectively, the sum of thirty-six million, nine hundred forty-four thousand, forty-three dollars (\$36,944,043), plus any interest that may have accrued between November 1, 2006 and the Effective Date of this Agreement at a rate of 5% per annum ("Settlement Amount"). On the

Effective Date of this Agreement, as defined in paragraph 32 herein, this sum shall constitute a debt due and immediately owing to the United States and the Participating States.

InterMune shall discharge its debt to the United States and the Medicaid Participating States under the following terms and conditions:

a. InterMune shall pay to the United States the principal sum of \$30,249,229 (the "Federal Settlement Amount"). InterMune shall pay the Federal Settlement Amount, plus interest accrued thereon at the rate of 5% per annum, in accordance with the payment schedule attached hereto as Exhibit A ("Payment Schedule"). Within 10 days after the Effective Date of this Agreement, InterMune shall pay the United States the initial fixed payment in the amount of \$4,093,925 ("Initial Payment"), plus any interest that may have accrued between November 1, 2006 and the Effective Date, and thereafter make principal payments with interest according to the schedule in Exhibit A.

b. All payments set forth in this Paragraph 1(a) shall be made to the United States by electronic funds transfer pursuant to written instructions provided by the Office of the United States Attorney for the Northern District of California. The entire principal balance of the Federal Settlement Amount or any portion thereof, plus any interest accrued on the principal as of the date of any prepayment, may be prepaid without penalty.

c. InterMune shall pay to the Medicaid Participating States the sum of \$6,694,814 ("Medicaid State Settlement Amount"). InterMune shall pay the Medicaid State Settlement Amount, plus interest accrued thereon at the rate of 5% per annum, in accordance with the Payment Schedule found at Exhibit A. Within 10 days after the Effective Date of this

Agreement, InterMune shall set aside \$906,075, plus any interest that may have accrued between November 1, 2006 and the Effective Date, into an interest-bearing account of its own choosing ("deposit account") as agreed upon between InterMune and the National Association of Medicaid Fraud Control Units Settlement Team (the "NAMFCU Team") and, upon reaching agreements with, and obtaining release from each of the Medicaid Participating States and receipt of written payment instructions from the NAMFCU Team, shall pay the State Settlement Amount plus any additional interest earned in the deposit account as directed by each settling Medicaid Participating State. Upon reaching final agreements with, and obtaining release from the Medicaid Participating States, InterMune shall thereafter make fixed pro rata payments according to the schedule in Exhibit A and as directed by each settling Medicaid Participating State. The entire principal balance of the Medicaid State Settlement Amount or any portion thereof, plus any interest accrued on the principal as of the date of any prepayment, may be prepaid without penalty.

d. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. If the Court does not accept the DPA as described in Preamble Paragraph D or refuses to impose the agreed upon disposition for whatever reason, this Agreement shall be null and void at the option of either the United States or InterMune. If either the United States or InterMune exercises this option, which option shall be exercised by notifying all Parties, through

counsel, in writing within ten (10) business days of the Court's decision, the Parties will not object to the voiding of this Agreement and the Agreement will be deemed rescinded. If this Agreement is rescinded, InterMune will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any such civil or administrative claims, actions or proceedings relating to the Covered Conduct which are brought by the United States within 90 calendar days of notification to all other Parties of that rescission, except to the extent such defenses were available before the Effective Date of this Agreement.

3. Subject to the exceptions in Paragraphs 4, 5, 6, 7 and 8, in consideration of the obligations of InterMune set forth in this Agreement, conditioned upon InterMune's payment in full of the Settlement Amount, subject to Paragraph 20 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement, as defined below), and subject to the Court's approval of the DPA described in Preamble Paragraph D, the United States, on behalf of itself, and its officers, agents, agencies, and departments, as set forth above, hereby fully and finally releases InterMune, its predecessors, subsidiaries, corporate parents and affiliates, successors and assigns, and current or former officers, directors, and employees, except as excluded in Paragraph 4, below, from any civil or administrative monetary claim that the United States has against InterMune under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; any statutory provision applicable to the federally-funded programs in this Agreement for which the Civil Division, United States Department of Justice, has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I,

§ 0.45(d); and common law claims for fraud, payment by mistake, unjust enrichment or disgorgement for the Covered Conduct.

4. Notwithstanding any term of this Agreement, the United States specifically does not herein release any person or entity from any of the following claims or liabilities: (a) any potential criminal, civil or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code); (b) any criminal liability; (c) any potential liability to the United States (or any agencies thereof) for any conduct other than the Covered Conduct; (d) any claims based upon obligations created by this Agreement; (e) except as explicitly stated in Paragraphs 5, 6, 7 and 8 of this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs; (f) any express or implied warranty claims or other claims for defective or deficient products and services; (g) any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct; (h) any claim based on a failure to deliver items or services due; or (i) any civil or administrative claims against individuals, including current and former directors, officers, and employees of InterMune, its predecessors, subsidiaries, and its corporate parent and affiliates, who, related to the Covered Conduct, receive written notification that they are the target of a criminal investigation, are criminally indicted or charged, or are convicted, or who enter into a criminal plea agreement.

5. In consideration of the obligations of InterMune set forth in this Agreement and in the Corporate Integrity Agreement (“CIA”), conditioned upon InterMune’s payment in full of the Settlement Amount, and subject to Paragraph 20 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement), the OIG-HHS agrees to

release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion against InterMune from Medicare, Medicaid or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities), for the Covered Conduct except as reserved in Paragraph 4 above, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude InterMune from the Medicare, Medicaid, or other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, above. InterMune will immediately begin implementing its obligations under the CIA upon execution of this Agreement.

6. In consideration of the obligations of InterMune set forth in this Agreement, conditioned upon InterMune's full payment of the Settlement Amount, and subject to Paragraph 20 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement or any payment under this Agreement), TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion or suspension from the TRICARE Program against InterMune and its predecessors, subsidiaries, corporate parents, affiliates, successors and assigns, or its current directors, officers or employees under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 4 above, and as reserved in this Paragraph. TMA expressly reserves its authority to exclude InterMune under 32

C.F.R. § 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct.

Nothing in this Paragraph precludes TMA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, above.

7. In consideration of the obligations of InterMune in this Agreement, conditioned upon InterMune's full payment of the Settlement Amount, and subject to Paragraph 20 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking debarment from FEHBP against InterMune and its predecessors, subsidiaries, corporate parents, affiliates, successors and assigns, or its current directors, officers or employees under 5 U.S.C. § 8902a or 5 C.F.R. Part 970 for the Covered Conduct, except as reserved in Paragraph 4, above. OPM expressly reserves all rights to comply with any statutory obligations to debar InterMune from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory debarment) based upon the Covered Conduct. Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, above.

8. In consideration of the obligations of InterMune set forth in this Agreement, conditioned upon InterMune's full payment of the Settlement Amount, and subject to Paragraph 20 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement or any payment under this Agreement), DSCP/DLA agrees to defer to the OIG-HHS for any contractor integrity issues arising from this settlement and the Covered Conduct.



Nothing in this Paragraph precludes DLA from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, above.

9. [REDACTED]

[REDACTED]

10. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

12. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

13. Upon execution of this Agreement by all parties, the United States will [REDACTED] [REDACTED] advise the Court that the parties have reached a civil settlement. Upon receipt of the full payments described in Paragraph 1(a) and (c) above and in Exhibit A, the United States [REDACTED] shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal with prejudice of the Civil Action pursuant to the terms of the Agreement.

14. In consideration of the obligations of the United States set forth in this Agreement, InterMune and its predecessors, subsidiaries, corporate parents and affiliates fully

and finally release the United States, its agencies (including, but not limited to, HHS, TMA, OPM and DVA), employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which they have asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to or arising from the United States' criminal and civil investigations of the Civil Action and the Covered Conduct.

15. [REDACTED]

16. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Federal or State payer, related to the Covered Conduct; and InterMune shall not resubmit to any Federal or State payer any previously denied claims related to the Covered Conduct, and shall not appeal any such denials of claims.

17. InterMune agrees to the following:

a. Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulations (FAR) 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh and 1396-1396y, and the regulations and official

program directives promulgated thereunder) incurred by or on behalf on InterMune, its present or former officers, directors, employees, shareholders, and agents in connection with: (1) the matters covered by this Agreement and the related DPA; (2) the United States' civil and criminal investigation of the matters covered by this Agreement; (3) InterMune's investigation, defense, and any corrective actions undertaken in direct response to the United States' civil and criminal investigations in connection with the matters covered by this Agreement (including attorneys' fees); (4) the negotiation and performance of this Agreement, the DPA, and the Medicaid State Settlement Agreement, (5) the payments made to the United States or any State pursuant to this Agreement, the DPA, or the Medicaid State Settlement Agreement and a [REDACTED] [REDACTED] (6) the negotiation of, and the obligations undertaken pursuant to the CIA, including to (i) retain an independent review organization to perform annual reviews as described in Section III.D of the CIA; and (ii) prepare and submit reports to the OIG-HHS, are unallowable costs on Government contracts with DVA, DLA and other agencies and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP. However, nothing in this Paragraph affects the status of costs that are not allowable based on any other authority applicable to InterMune. (All costs described or set forth in this Paragraph 17(a) are hereafter, "unallowable costs").

b. Future Treatment of Unallowable Costs: If applicable, these unallowable costs will be separately estimated and accounted for by InterMune, and it will not charge such unallowable costs directly or indirectly to any contracts with the United States or any State Medicaid Program, or seek payment for such unallowable costs through any cost report, cost

statement, information statement, or payment request submitted by them or any of their subsidiaries to Medicare, Medicaid, TRICARE, FEHBP, DLA or DVA.

c. Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, InterMune further agrees that within 90 days of the Effective Date of this Agreement, it will identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, DLA, DVA, and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by InterMune or any of its subsidiaries, and will request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. InterMune agrees that the United States, at a minimum, will be entitled to recoup from InterMune any overpayment plus applicable interest as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment. Any payment due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by InterMune or any of its subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on InterMune's or any of its subsidiaries' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the unallowable costs

described in this Paragraph.

18. InterMune agrees that it will not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents or sponsors. InterMune waives any causes of action against these beneficiaries or their parents or sponsors based upon the claims for payment covered by this Agreement.

19. InterMune expressly warrants that it has reviewed its financial situation and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and expects to remain solvent following the payments to the United States hereunder. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (a) have intended that the mutual promises, covenants and obligations set forth herein constitute a contemporaneous exchange for new value given to InterMune, within the meaning of 11 U.S.C. § 547(c)(1), and (b) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange.

20. In the event InterMune or any other party commences, within 91 days of the Effective Date of this Agreement (defined below), or of any payment made hereunder, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization or relief of debtors, (a) seeking to have any order for relief of InterMune's debts, or seeking to adjudicate InterMune as bankrupt or insolvent, or (b) seeking appointment of a receiver, trustee, custodian or other similar official for InterMune for all or any substantial part of its assets, InterMune agrees as follows:

a. InterMune's obligations under this Agreement may not be avoided

pursuant to 11 U.S.C. § 547 or 548, and InterMune will not argue or otherwise take the position in any such case, proceeding or action that: (i) InterMune's obligations under this Agreement may be avoided under 11 U.S.C. § 547 or 548; (ii) InterMune was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to InterMune;

b. In the event that InterMune's obligations hereunder are avoided for any reason, including, but not limited to, the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action or proceeding against InterMune for the claims that would otherwise be covered by the releases provided in this Agreement. If the United States chooses to do so, InterMune agrees that, for purposes only of any case, action, or proceeding referenced in the first clause of this Paragraph, (i) any such claims, actions or proceedings brought by the United States (including any proceedings to exclude InterMune from participation in Medicare, Medicaid, or other Federal Health Care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. Section 362(a) as a result of the action, case or proceeding described in the first clause of this Paragraph, and that InterMune will not argue or otherwise contend that the United States' claims, actions or proceedings are subject to an automatic stay; (ii) that InterMune will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any such civil or administrative claims, actions or proceedings which are

brought by the United States within 30 calendar days of written notification to InterMune that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available before the Effective Date of this Agreement; and (iii) the United States and the Participating States have valid claims against InterMune in at least the aggregate amount of the Settlement Amount and they may pursue their claims, inter alia, in the case, action or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding; and

c. InterMune acknowledges that its agreement in this Paragraph is provided in exchange for valuable consideration provided in this Agreement.

21. In the event that InterMune fails to pay any and all of the payments owed pursuant to this Agreement within 30 calendar days of the due date ("Default"), any dismissals as to InterMune shall, at the United States' option, be null and void, and the Settlement Amount referenced in Paragraph 1 above, less any payments already made, shall become immediately due and payable and shall bear interest at the Medicare interest rate (per 42 C.F.R. part 405.378) as of the date of Default until payment of the Settlement Amount is made in full.

Furthermore, in the event of a breach of the payment provisions as described in the preceding paragraph, the United States may at its option: 1) rescind its releases; 2) offset the remaining unpaid balance of the Settlement Amount from any amounts due and owing to InterMune by any department, agency, or agent of the United States at the time of Default; 3) reinstitute an action or actions against InterMune in this Court; and 4) InterMune agrees not to contest any draw, offset, or collection action undertaken by the United States pursuant to this



Paragraph, either administratively or in any court.

In the event of a Default of any payment under this Agreement, InterMune agrees to pay the United States all reasonable costs of collection and enforcement of this Agreement, including attorneys' fees and expenses. In the event the United States reinstitutes an action under this Paragraph, InterMune expressly agrees not to plead, argue, or otherwise raise any defense under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims, which: (a) are filed by the United States within 30 calendar days of written notification to InterMune that this Agreement has been made a nullity, and (b) relates to the Covered Conduct, except to the extent these defenses were available on September 4, 2006.

22. In the event of Default as defined in Paragraph 21 above, OIG-HHS may exclude InterMune from participating in all Federal health care programs until InterMune pays the Settlement Amount and reasonable costs as set forth in Paragraphs 1 and 21 above. OIG-HHS will provide written notice of any such exclusion to InterMune. InterMune waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion InterMune wishes to apply for reinstatement, InterMune must submit a written request for reinstatement to the OIG in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. InterMune will not be reinstated unless and until the OIG approves such request for reinstatement.

23. InterMune has provided financial statements to the United States and the United States has relied on the accuracy and completeness of these financial statements in reaching this

Agreement. If the United States learns that the historical financial statements contained in InterMune SEC filings made between May 2005, and the Effective Date, either (a) failed to disclose a material non-contingent asset or assets in which InterMune had an interest (a “Material Nondisclosure”); or (b) contained any other knowing, material misrepresentation or omission regarding the financial condition of InterMune (a “Knowing Material Misrepresentation”), the United States may at its option pursue relief under this Paragraph 23 as follows: (a) the United States shall provide InterMune with written notice of the nature of the Material Nondisclosure or Knowing Material Misrepresentation; (b) within ten (10) calendar days of the date of the written notice, InterMune shall provide the United States, in writing, with any explanation it may have regarding the Material Nondisclosure or Knowing Material Misrepresentation referenced in the written notice; (c) if unsatisfied with InterMune’s explanation, as determined in its sole and absolute discretion, the United States may file an action seeking relief under this Paragraph 23 in which action the United States shall bear the burden of establishing by a preponderance of the evidence the Material Nondisclosure or Knowing Material Misrepresentation; (d) if the court finds a Material Nondisclosure or Knowing Material Misrepresentation, then – (i) the Settlement Amount shall be increased by one hundred percent (100%) of the amount of the Material Nondisclosure or Knowing Material Misrepresentation; (ii) the remaining unpaid principal portion of the Settlement Amount (including the increase specified in subparagraph (d)(i) above) shall become accelerated and immediately due and payable, with interest at a simple rate of 5% from the Effective Date of this Agreement to the date of the court finding, and at the Medicare interest rate (per 42 C.F.R. part 405.378) from the date of the court finding until the date of

payment; (iii) the United States may offset the remaining unpaid balance of the Settlement Amount (inclusive of interest and the increase specified in subparagraph (d)(i) above) from any amounts due and owing to InterMune by any department, agency, or agent of the United States; and (iv) InterMune shall immediately pay the United States all reasonable costs incurred in the action seeking relief under this Paragraph 23, including attorney's fees and expenses.

24. If, after the Effective Date of this agreement and before the company has made all payments required pursuant to Paragraph 1 of this Agreement, the company obtains a cumulative total of more than \$150,000,000.00 in cash financing from (1) license fees and milestone payments paid to the company pursuant to partnering agreements, (2) external debt financing, and/or (3) external equity financing, the company shall notify the United States and apply twenty percent (20%) of the excess over \$150,000,000.00 ("excess cash amount") to make advance payments against the Settlement Amount. The company shall make the advance payment(s) first by paying the outstanding principal owed (plus any interest accrued on that principal through the advance payment date) in 2011 and shall continue to make such advance payments in reverse chronological order until the excess cash amount is reduced to zero. The payment schedule referenced in Exhibit A shall remain in effect until the balance of the Settlement Amount is paid off. Cash financing, for purposes of this paragraph, is limited to the sources enumerated in the first sentence of this paragraph and shall expressly exclude any increase in operating revenues after the Effective Date or reimbursement of research or development expenses from a partner. Advance payments made by the company pursuant to this paragraph shall not exceed \$10,000,000.00 in any single calendar year. Further, in the event InterMune is sold (either

through an asset sale or an equity sale) or merged into another non-affiliated entity, then all remaining payments owed pursuant to the Settlement Agreement, are accelerated and become immediately due and payable.

In addition to notifying the United States when it has obtained more than \$150,000,000 in cash financing, Intermune will be required to provide the United States with notice within ten days of each financing arrangement or agreement (agreement) it obtains after the Effective Date of the settlement after the cumulative financing described in the preceding paragraph totals \$150,000,000, along with a copy of each such financing agreement. InterMune further agrees that it shall pay the U.S. all amounts required under this provision within 10 days following receipt of external financing which causes a prepayment under this paragraph. Amounts that are due under this paragraph and not paid when due will be considered amounts in Default. Default amounts are subject to the Default provisions (except that Default will be effective immediately and not within 30 days of the due date) contained in this Settlement Agreement as specified in paragraph 21, including the Default rate of interest at the Medicare interest rate (per 42 C.F.R. part 405.378) beginning as of the date of Default until payment of the Settlement Amount is made in full.

25. InterMune waives and will not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

26. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

27. Except as otherwise stated herein, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity.

28. Nothing in any provision of this Agreement constitutes an agreement by the United States, InterMune [REDACTED] concerning the characterization of the Settlement Amount [REDACTED] for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

29. Except as expressly provided in this Agreement, each party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

30. This Agreement is governed by the laws of the United States. The Parties agree that the United States District Court for the Northern District of California shall retain jurisdiction over this Agreement until all the terms and conditions have been completely satisfied. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the United States District Court for the Northern District of California, [REDACTED] except that disputes arising under the CIA shall be resolved through the dispute resolution provisions set forth in the CIA.

31. The undersigned InterMune signatories represent and warrant that they are

authorized by their Board of Directors to execute this Agreement. [REDACTED]

[REDACTED] The undersigned United States signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement on behalf of the United States through their respective agencies and departments, and, in the case of the OIG-HHS and TMA, on behalf of their respective Departments.

32. This Agreement is effective on the later of (1) the date of signature of the last signatory to the Agreement, or (2) the date the Court approves the DPA as described in Preamble Paragraph D (the "Effective Date"). Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

33. This Agreement shall be binding on all successors, transferees, heirs and assigns of the Parties.

34. This Agreement and Exhibit A attached hereto, together with the CIA, and the DPA described in Preamble Paragraphs C and D, constitute the complete agreement between the Parties with regard to the Covered Conduct. This Agreement may not be amended except by written consent of all the Parties, except that only InterMune and OIG-HHS must agree in writing to a modification of the CIA, without the consent of any other party to this Agreement or the DPA.

35. InterMune [REDACTED] hereby consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

36. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.

UNITED STATES OF AMERICA



By:

\_\_\_\_\_  
ALEX G. TSE  
Assistant United States Attorney  
United States Attorney's Office  
Northern District of California

Dated: 10/25/06

By:

\_\_\_\_\_  
ANDY J. MAO  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

Dated:

By:

\_\_\_\_\_  
GREGORY E. DEMSKE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services

Dated:

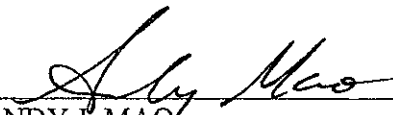
UNITED STATES OF AMERICA

By:

\_\_\_\_\_  
ALEX G. TSE  
Assistant United States Attorney  
United States Attorney's Office  
Northern District of California

Dated:

By:

\_\_\_\_\_  
  
ANDY J. MAO  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

Dated:

10/25/06

By:

\_\_\_\_\_  
GREGORY E. DEMSKE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services

Dated:



UNITED STATES OF AMERICA

By:

\_\_\_\_\_  
ALEX G. TSE  
Assistant United States Attorney  
United States Attorney's Office  
Northern District of California


Dated:

By:

\_\_\_\_\_  
ANDY J. MAO  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

Dated:

By:

  
\_\_\_\_\_  
GREGORY E. DEMSKE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services

Dated:

10/25/06


By: Kathleen McGettigan  
KATHLEEN McGETTIGAN  
Deputy Associate Director  
Center for Retirement & Insurance Services United States Office of Personnel  
Management

Dated: 10/20/2006

By: J. David Cope  
J. DAVID COPE  
Assistant Inspector General for Legal Affairs \  
United States Office of Personnel Management

Dated: 10/20/2006

By:

  
LAUREL C. GILLESPIE  
Deputy General Counsel  
TRICARE Management Activity  
United States Department of Defense

Dated: 24 Oct 06

By:

\_\_\_\_\_  
SUSAN CHADICK  
Deputy General Counsel  
Defense Logistics Agency

Dated:

**InterMune, Inc. Settlement Agreement**

By:

\_\_\_\_\_  
LAUREL C. GILLESPIE  
Deputy General Counsel  
TRICARE Management Activity  
United States Department of Defense

Dated:

By:

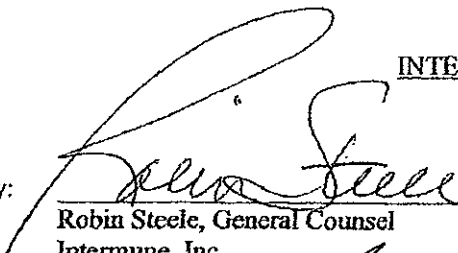
\_\_\_\_\_  
*Susan Chadick*  
SUSAN CHADICK  
Deputy General Counsel  
Defense Logistics Agency

Dated:

*October 25, 2006*

INTERMUNE, INC.

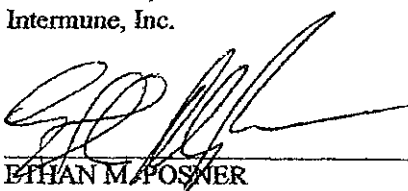
By:

  
Robin Steele, General Counsel  
Intermune, Inc.

Dated:

*October*  
*24, 2006*

By:

  
ETHAN M. POSNER  
Covington & Burling LLP

Dated:

*10-24-06*

[REDACTED]

[REDACTED]

[REDACTED]

By:

[REDACTED]

Dated:

By:

[REDACTED]

Dated:

[REDACTED]

## EXHIBIT A: PAYMENT SCHEDULE

### TOTAL PAYMENT

Year	Payment	Interest at 5%	Principal	Balance
				36,944,043.50
11/1/2006	5,000,000.00	-	5,000,000.00	31,944,043.50
11/1/2007	5,000,000.00	1,597,202.18	3,402,797.83	28,541,245.68
11/3/2008	6,500,000.00	1,427,062.28	5,072,937.72	23,468,307.96
11/2/2009	7,000,000.00	1,173,415.40	5,826,584.60	17,641,723.36
11/1/2010	9,000,000.00	882,086.17	8,117,913.83	9,523,809.52
11/1/2011	10,000,000.00	476,190.48	9,523,809.52	0.00
Total	42,500,000.00		36,944,043.50	

### PAYMENT TO THE UNITED STATES

Year	Payment	Interest at 5%	Principal	Balance
				30,249,228.50
11/1/2006	4,093,924.98	-	4,093,924.98	26,155,303.52
11/1/2007	4,093,924.98	\$1,307,765	2,786,159.80	23,369,143.72
11/3/2008	5,322,102.47	\$1,168,457	4,153,645.29	19,215,498.43
11/2/2009	5,731,494.97	\$960,775	4,770,720.05	14,444,778.38
11/1/2010	7,369,064.96	\$722,239	6,646,826.04	7,797,952.34
11/1/2011	8,187,849.96	\$389,898	7,797,952.34	0.00
Total	34,798,362.32	4,549,133.82	30,249,228.50	

### PAYMENT TO THE MEDICAID PARTICIPATING STATES

Year	Payment	Interest at 5%	Principal	Balance
				6,694,815.00
11/1/2006	906,075.02	-	906,075.02	5,788,739.98
11/1/2007	906,075.02	\$289,437	616,638.02	5,172,101.96
11/3/2008	1,177,897.53	\$258,605	919,292.43	4,252,809.53
11/2/2009	1,268,505.03	\$212,640	1,055,864.55	3,196,944.97
11/1/2010	1,630,935.04	\$159,847	1,471,087.79	1,725,857.18
11/1/2011	1,812,150.04	\$86,293	1,725,857.18	0.00
Total	7,701,637.68	1,006,822.68	6,694,815.00	

# Attachment C



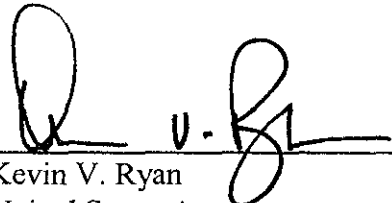
**Attachment C - Acknowledgment of Agreement**

This Agreement supersedes all prior, if any, written or oral understandings, promises, and/or conditions between the Department and InterMune, Inc., with the exception of the Civil Settlement Agreement incorporated herein, the Corporate Integrity Agreement referred to herein, and the letter from Ethan Posner to the Department dated October 9, 2006. No additional promises, agreements, and conditions have been entered into and none will be entered into unless in writing and signed by all the parties.

**On Behalf of the United States Department of Justice:**

DATE

10.24.06

  
Kevin V. Ryan  
United States Attorney  
Northern District of California

  
Ioana Petrou  
Assistant United States Attorney

**On Behalf Of InterMune, Inc.**

DATE

Robin Steele  
Senior Vice President and General Counsel  
InterMune, Inc.  
3280 Bayshore Boulevard  
Brisbane, CA 94005

DATE

Ethan Posner  
Covington & Burling  
Counsel to InterMune, Inc.

1 Attachment C - Acknowledgment of Agreement

2  
3 This Agreement supersedes all prior, if any, written or oral understandings, promises,  
4 and/or conditions between the Department and InterMune, Inc., with the exception of the Civil  
5 Settlement Agreement incorporated herein, the Corporate Integrity Agreement referred to herein,  
6 and the letter from Ethan M. Posner to the Department dated October 9, 2006. No additional  
7 promises, agreements, and conditions have been entered into and none will be entered into unless  
8 in writing and signed by all the parties.

9 **On Behalf of the United States Department of Justice:**

10  
11  
12 DATE

Kevin V. Ryan  
United States Attorney  
Northern District of California

13  
14  
15  
16 Ioana Petrou  
Assistant United States Attorney

17  
18  
19 **On Behalf Of InterMune, Inc.**

20 *October 24, 2006*  
21 DATE

*Robin Steele*  
Robin Steele  
Senior Vice President and General Counsel  
InterMune, Inc.  
3280 Bayshore Boulevard  
Brisbane, CA 94005

22  
23  
24  
25 *10-24-06*  
26 DATE

*Ethan M. Posner*  
Ethan M. Posner  
Covington & Burling  
Counsel to InterMune, Inc.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that he is an employee of the office of the United States Attorney, Northern District of California and is a person of such age and discretion to be competent to serve papers. The undersigned certifies that he caused copies of

**[PROPOSED] DEFERRED PROSECUTION AGREEMENT**

in the case of **United States v. Intermune, Inc., No. CR 06-0707 JSW**  
to be served on the parties in this action, addressed as follows which are the last known addresses and fax numbers:

**Barbara Hoffman  
Covington & Burling LLP  
1330 Avenue of the Americas  
New York, New York 10019  
212-841-1143  
Fax: 646-441-9143  
bhoffman@cov.com**

\_\_\_\_ (By Personal Service), I caused such envelope to be delivered by hand to the person or offices of each addressee(s) above.

\_\_\_\_ (By Facsimile), I caused each such document to be sent by Facsimile to the person or offices of each addressee(s) above.

\_\_\_\_ (By Mail), I caused each such envelope, with postage thereon fully prepaid, to be placed in the United States mail at San Francisco, California.

X  (By Fed Ex), I caused each such envelope to be delivered by FED EX to the address listed above.

I declare under penalty of perjury that the foregoing is true and correct.

October 26, 2006

  
TYLE L. DOERR  
United States Attorney's Office